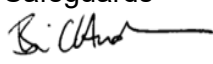




UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 21, 2021

MEMORANDUM TO: John W. Lubinski, Director
Office of Nuclear Material Safety and Safeguards

FROM: Brian C. Anderson, Chief  Signed by Anderson, Brian
State Agreement and Liaison Programs Branch on 07/21/21
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards

SUBJECT: DRAFT INTEGRATED MATERIALS PERFORMANCE
EVALUATION PROGRAM (IMPEP) REVIEW REPORT FOR THE
CONSOLIDATED U.S. NUCLEAR REGULATORY COMMISSION
MATERIALS PROGRAM

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the review of Agreement State and NRC radiation control programs. The enclosed draft IMPEP report documents the results of the June 7-11, 2021 NRC review, which was conducted remotely due to travel restrictions associated with the COVID-19 Public Health Emergency. Between April 13 and June 3, 2021, the team conducted eight in-person and two remote inspector accompaniments. The team's preliminary findings were discussed with you and your staff on the last day of the review. The team's proposed recommendations are that the NRC radiation control program be found adequate to protect public health and safety.

The NRC conducts periodic reviews of radiation control programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials. The IMPEP process uses a team comprised of Agreement State and NRC staff to perform the reviews. All reviews use common criteria in the assessment and place primary emphasis on performance. The final determination of adequacy of each program, based on the team's report, is made by the Chair of the Management Review Board (MRB) after receiving input from the MRB members. The MRB is composed of NRC senior managers and an Agreement State program manager.

In accordance with procedures for implementation of IMPEP, we are providing this draft report for your review, and comment prior to submitting the report to the MRB. Comments are requested within 4 weeks from your receipt of this letter.

CONTACT: Duncan White NMSS/MSST
301-415-2598

The team will review the response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. The MRB meeting is scheduled to be conducted remotely on September 14, 2021, via Microsoft Teams. Details regarding the schedule for this public meeting, and the links for participants to access the meeting, will be provided to you several weeks prior to the meeting.

If you have any questions regarding the enclosed report, please contact Duncan White at duncan.white@nrc.gov.

Enclosure:
2021 Draft IMPEP Report

cc: R. Lewis, NMSS
K. Williams, NMSS/MSST
P. Holahan, NMSS/DUWP
D. Lew, RI
J. Giessner, RIII
S. Morris, RIV

SUBJECT: MEMO TO J. LUBINSKI RE: INTEGRATED MATERIALS PERFORMANCE
EVALUATION PROGRAM (IMPEP) REVIEW REPORT FOR THE
CONSOLIDATED U.S. NUCLEAR REGULATORY COMMISSION MATERIALS
PROGRAM DATE July 21, 2021

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OFFICE	NMSS/MSST/SLPB/PM	NMSS/MSST/SLPB/TL	NMSS/MSST/SLPB/PM
NAME	THood	DWhite	RJohnson
DATE	07/01/2021	07/01/2021	07/01/2021
OFFICE	NMSS/MSST/RRS	OCHCO/DCHCO	NMSS/MSST
NAME	ERaphael	DCollins	BAnderson
DATE	07/06/2021	07/16 /2021	07/21/2021



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NRC PROGRAM

JUNE 7 -11, 2021

DRAFT REPORT

Enclosure

EXECUTIVE SUMMARY

The first consolidated Integrated Materials Performance Evaluation Program (IMPEP) review of the Nuclear Regulatory Commission (NRC) radiation control program was conducted in the period from April – June 2021. This included in-person and remote inspector accompaniments between April 13 and June 3, 2021, and a focused review week from June 7-11, 2021. Due to travel restrictions associated with the COVID-19 Public Health Emergency, the team's activities during the focused review week were conducted remotely. Additionally, this was the first IMPEP review of the NRC materials program that considered licensing activities for complex decommissioning and uranium recovery sites. These licensing functions were reviewed under the performance indicators Technical Quality of Licensing and Uranium Recovery Program, respectively.

Prior to this 2021 review, IMPEP reviews of the NRC treated the NRC regions and offices as being separate programs. As such, the IMPEP reviews of the regions and offices were conducted at different times and focused on specific activities conducted under the purview of individual NRC offices. The review periods for this review were based on the date of the Region's or Office's last review and for complex decommissioning and uranium recovery activities, a period of 3 years, and are as follows:

- Region I: April 2015 – June 2021
- Region III: July 2017 – June 2021
- Region IV: April 2019 – June 2021
- Sealed Source and Device program: December 2014 – June 2021
- Uranium Recovery Program: June 2018 – June 2021

The team found the NRC program's performance to be satisfactory for all performance indicators. The team did not make any new recommendations and determined that the NRC has taken sufficient actions to address the recommendation from the 2014 Sealed Source and Device Evaluation Program IMPEP.

Accordingly, the team recommends that: the NRC radiation control program be found adequate to protect public health and safety; the recommendation from the 2014 Sealed Source and Device Evaluation Program IMPEP review be closed; and that the next IMPEP review take place in approximately 5 years with a periodic meeting in approximately 2.5 years.

1.0 INTRODUCTION

The Nuclear Regulatory Commission (NRC) review was conducted from June 7-11, 2021, by a team of technical staff members from the NRC, the Commonwealth of Kentucky, and the States of Arizona, Louisiana, Minnesota, New Jersey, Ohio, and Texas. This review was conducted remotely due to travel restrictions imposed by the COVID-19 Public Health Emergency (PHE). The team conducted eight in-person and two remote inspector accompaniments between April 13 and June 3, 2021. Team members are identified in Appendix A.

The review was conducted in accordance with NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated July 24, 2019. The team also used Temporary Instruction (TI) 003, "Evaluating the Impacts of the Coronavirus Disease 2019 Public Health Emergency as Part of IMPEP," dated October 21, 2020, to evaluate the impacts of the COVID-19 PHE. Preliminary results of the review, which covered the period of December 2014 to June 2021, were discussed with the NRC managers on the last day of the review.

This was the first IMPEP review of the consolidated NRC radiation control program as directed by Steven West, Deputy Executive Director for Materials, Waste, Research, State, Tribal, Compliance, Administration and Human Capital Programs, in a memo dated January 22, 2020 (see Agencywide Documents Access and Management System Accession (ADAMS) Accession Number [ML19331A856](#)). Additionally, this was the first IMPEP review of the NRC materials program that considered licensing activities for complex decommissioning and licensing and oversight of uranium recovery sites. These functions were reviewed under the performance indicators Technical Quality of Licensing and Uranium Recovery Program, respectively.

Prior to this 2021 review, IMPEP reviews of the NRC treated the NRC regions and offices as being separate programs. As such, the IMPEP reviews of the regions and offices were conducted at different times and focused on specific activities conducted under the purview of individual NRC offices. The review periods for this review were based on the date of the Region's or Office's last review. For the licensing activities for complex decommissioning and licensing and oversight of uranium recovery sites, a period of 3 years was used. Complex decommissioning was reviewed under the Technical Quality of Licensing Actions performance indicator. Accordingly, the review periods for the individual NRC components were as follows:

- Region I: April 2015 – June 2021
- Region III: July 2017 – June 2021
- Region IV: April 2019 – June 2021
- Sealed Source and Device Program : December 2014 – June 2021
- Uranium Recovery Program: June 2018 – June 2021

Using June 2021 as the end point of the review period for this IMPEP establishes a single point for the start of the next review period such that future IMPEP reviews of the NRC will have a consistent review period for all components of the NRC program.

In preparation for the review, the NRC received a questionnaire (ADAMS Accession Number [ML21015A420](#)) addressing the common performance indicators and applicable non-common performance indicators. The NRC's consolidated questionnaire response is available in ADAMS under Accession Number [ML21182A357](#).

The NRC radiation control program is administered by the MSST and DUWP Division Directors in NMSS and the Regional Administrators in Regions I, III, and IV. The Director of the Office of Nuclear Material Safety and Safeguards has overall programmatic responsibility for the NRC's radiation control program. The NRC organization charts are available in ADAMS (Accession Number [ML21180A468](#)). At the time of the review, the NRC regulated 2,096 specific licenses authorizing possession and use of radioactive materials and 157 sealed source and device registrations. The review focused on the NRC's radiation control program as carried out under Section 161 of the Atomic Energy Act of 1954, as amended.

The team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the NRC's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP reviews for the NRC radiation control program were conducted from December 2014 to April 2019, and the associated IMPEP reports are available at the following ADAMS Accession Numbers:

- Region I, July 15, 2015, [ML15174A051](#)
- Region III, November 16, 2017, [ML17289A092](#)
- Region IV, July 18, 2019, [ML19184A011](#)
- Sealed Source and Device Evaluation Program, March 26, 2015, [ML15068A034](#)
- Uranium Recovery Program (inspection only), July 18, 2019, [ML19184A011](#)

Previous reviews of the NRC program were satisfactory for all performance indicators. The overall results of the program reviews are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: None
Offices Reviewed: Regions I, III, and IV

Status of Materials Inspection Program: Satisfactory
Recommendation: None
Offices Reviewed: Regions I, III, and IV

Technical Quality of Inspections: Satisfactory
Recommendation: None
Offices Reviewed: Regions I, III, and IV

Technical Quality of Licensing Actions: Satisfactory
Recommendation: None
Offices Reviewed: Regions I, III, and IV

Technical Quality of Incident and Allegation Activities: Satisfactory
Recommendation: None
Offices Reviewed: Regions I, III, and IV

Sealed Source and Device (SS&D) Evaluation Program: Satisfactory
Office Reviewed: NMSS/MSST

Recommendation: Following the 2014 IMPEP review the MRB recommended: “The Branch develop and implement a mechanism to obtain missing historical documents referenced in the SS&D registration certificates transferred from the State of Georgia.”

Status: To address the recommendation NRC staff worked with the State of Georgia and certificate holders to locate the missing reference documents. Staff determined that 19 SS&D registration certificates were missing reference documents. Staff determined that seven of the registration certificates were inactive and immediately transferred to an inactive status. Staff identified and obtained all the missing reference documents. Staff documented the findings in an internal closure in a memorandum dated January 20, 2016. Therefore, the team recommends that this recommendation be closed.

Uranium Recovery Program (inspection only): Satisfactory

Recommendation: None

Office Reviewed: Region IV

Overall finding from each of the previous IMPEP reviews summarized above: Adequate to protect public health and safety.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC radiation control program. These indicators are: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs and could affect public health and safety. Apparent trends in staffing must be assessed. Review of staffing also requires consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

a. Scope

The team used the guidance in State Agreements procedure SA-103, “Reviewing the Common Performance Indicator: Technical Staffing and Training,” and evaluated the NRC’s performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Qualification criteria for new technical staff are established and are followed, or qualification criteria will be established if new staff members are hired.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

At the time of the review, the team determined that the NRC's radiation control program was comprised of 73 technical staff members and 38 support staff members including management, regional state agreements officers, technical assistants, and administrative staff. This equals approximately 107.2 full time equivalent (FTE) staff for the radiation control program. At the time of the review, 5 vacancies were in the process of being filled. During the review period, 32 staff members left the program, and 30 staff members were hired. The positions were vacant for approximately 6 months or less. The team concluded that the NRC had sufficient personnel with the required skill sets to support the size and scope of its radiation control program.

The NRC implements the training and qualification program specified in Inspection Manual Chapter (IMC) 1248, "Qualification Programs for Federal and State Materials and Environmental Management Programs," and applicable appendices. The team found that refresher training for technical staff was in accordance with the criteria specified in IMC 1248. The team also found no significant impacts to the training schedules for new staff in the year 2020 as a result of the limited availability of training courses during the COVID 19 PHE.

c. Evaluation

The team determined that, during the review period, the NRC met the performance indicator objectives listed in Section 3.1.a. Based on the criteria in MD 5.6, the team recommends that the NRC's performance with respect to the indicator, Technical Staffing, and Training, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

3.2 Status of Materials Inspection Program

Inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety and security practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and type of radioactive material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated the NRC's performance with respect to the following performance indicator objectives:

- Initial inspections and inspections of Priority 1, 2, and 3 licensees are performed at the prescribed frequencies (<https://www.nrc.gov/materials/miau/mat-toolkits.html>).
- Deviations from inspection schedules are normally coordinated between technical staff and management.

- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections, or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 2800, and other applicable guidance.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection), as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports."

b. Discussion

The NRC performed 1,282 Priority 1, 2, 3, and initial inspections during the review period. The NRC conducted 4 (or less than 1 percent) of Priority 1, 2, 3, and initial inspections overdue. The team identified one overdue initial inspection at the time of the review (Region IV). This inspection is in progress, but remains open due to escalated enforcement. Of the 1282 Priority 1, 2, 3, and initial inspections noted above, 3 additional initial inspections were performed overdue due to impacts related to the COVID-19 PHE. TI-003, states, in part, that for inspections that exceed the scheduling window as described in IMC 2800 with overdue dates falling inside the COVID-19 PHE, the number of overdue inspections impacted by the COVID-19 PHE should be noted in the report but not be counted in the calculation of overdue inspections described in Appendix A of State Agreements procedure SA-101, provided that the Program continues to maintain health, safety, and security. Therefore, the team did not include these 3 inspections in their calculation. Based on the limited number of overdue inspections completed during the review period and the timely completion of nearly all inspections, the team concluded that NRC continued to maintain health, safety, and security during the COVID-19 PHE.

The team's review of 25 inspection reports found that the issuance of all cases meets the timeliness criteria in IMC 2800.

c. Evaluation

The team determined that, during the review period, the NRC met the performance indicator objectives listed in Section 3.2.a. Based on the criteria in MD 5.6, the team recommends that the NRC's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide reasonable assurance that licensee activities are carried out in a safe and secure manner. Accompaniments of inspectors performing inspections, and the critical evaluation of inspection records, are used to assess the technical quality of an inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated the

NRC's performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance, and assure consistent application of inspection policies.
- For Programs with separate licensing and inspection staffs, procedures are established, and followed to provide feedback information to license reviewers.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated 25 inspection reports and enforcement documentation, and interviewed inspectors involved in materials inspections conducted during the review period. The team reviewed casework for inspections conducted by 21 of the NRC's regional inspectors and covered medical, industrial, commercial, academic, research, and service provider licenses.

Team members conducted eight in-person and two remote inspector accompaniments between April 13 and June 3, 2021, covering all NRC regions. No performance issues were noted during the accompaniments. The team found that inspectors were well-prepared and thorough, and assessed the impact of licensed activities on health, safety, and security. Inspectors observed the use of radioactive materials when possible and interviewed licensee staff. Inspectors used open-ended questions and were able to develop a basis of confidence that radioactive materials were being used safely and securely. Any findings observed were brought to the user's attention at the time of the inspection and again to the licensee's management during the inspection closeout. The inspector accompaniments are identified in Appendix B.

The team found that the COVID-19 PHE had minimal impact on the technical quality of inspections. Only a few accompaniments by supervisors were unable to be performed. TI-003, states, in part, that the number of supervisory accompaniments that were not performed due to the COVID-19 PHE should be noted in the report but should not be considered in the overall indicator rating, provided that the Program continues to maintain health, safety, and security. Therefore, the team did not include these missed inspector accompaniments. Based on the limited number of missed accompaniments and the fact that these missed inspector accompaniments were all due to the impacts of the COVID-19 PHE the team concluded that NRC continued to maintain health, safety, and security during the COVID-19 PHE.

The team noted that violations were well documented and clearly articulated in inspection reports and related enforcement documents. Observations were clearly described, and findings were well supported. The team determined that the Offices conducting inspections had sufficient quantities and type of instrumentation to support inspection activities.

c. Evaluation

The team determined that, during the review period, the NRC met the performance indicator objectives listed in Section 3.3.a. Based on the criteria in MD 5.6, the team recommends that the NRC's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, implementation of those procedures, and documentation of communications, and associated actions between the NRC licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated the NRC's performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements are consistent with current regulatory guidance (e.g., pre-licensing guidance, Title 10 *Code of Federal Regulation* (CFR) Part 37, financial assurance, etc.).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk-significant radioactive materials are appropriately implemented including the physical protection of Category 1 and Category 2 quantities of radioactive material (10 CFR Part 37).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, the NRC performed 1,669 radioactive materials licensing actions. The team evaluated 28 of those licensing actions distributed across the NRC Program. The licensing actions selected for review included 4 new applications, 6 amendments, 5 renewals, 2 terminations, 2 financial assurance, 5 changes of control, 2 bankruptcies, and 2 decommissioning actions.

The casework evaluated by the team included the following license types and actions: medical broad scope and diagnostic, accelerator, veterinary, manufacturing and distribution, research and development, limited scope academic, nuclear pharmacy, gauges, complex decommissioning, change of control, financial assurance, and bankruptcy.

The team noted that 4 of the renewed licenses examined by the team during the period November 2020 through June 2021 had multiple program codes with non-standard license conditions. The team concluded that the use of the non-standard conditions did not have an adverse impact on the safe use of radioactive material. Subsequent to the review, MSST issued an internal memorandum, dated June 15, 2021, which provided a revision to the procedure for reviewing, and updating the standard license conditions in materials licenses that also addressed the use of non-standard license conditions during license renewal.

c. Evaluation

The team determined that, during the review period, the NRC met the performance indicator objectives listed in Section 3.4.a. Based on the criteria in MD 5.6, the team recommends that the NRC's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents, and allegations of safety concerns can have a direct bearing on public health, safety, and security. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal, and external coordination, timely incident reporting, and investigative and follow-up actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated the NRC's performance with respect to the following performance indicator objectives:

- Incident response, and allegation procedures are in place, and followed.
- Response actions are appropriate, well-coordinated, and timely.
- Onsite responses are performed when incidents have potential health, safety, or security significance.
- Appropriate follow-up actions are taken to ensure prompt compliance by licensees.
- Follow-up inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED) and closed when all required information has been obtained.
- Allegations are reviewed in a prompt, appropriate manner.

- Concerned individuals are notified within 30 days, of the review's conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 213 incidents were reported to the NRC. The team noted that two incidents involving leaking sources were not reported to NMED. Once identified to the NRC staff, the incidents were promptly added to NMED. The team evaluated 22 radioactive materials incidents which included 5 lost or stolen radioactive materials, 5 medical events, 3 damaged equipment, 2 leaking sources, 2 transportation events, 2 contamination events, and 3 equipment malfunctions. When notified of an incident, management, and staff meet to discuss the incident and determine the appropriate level of response, which can range from an immediate response to reviewing the incident during the next routine scheduled inspection. Those determinations are made based on both the circumstances and the health and safety significance of the incident. The team found that the NRC's evaluation of incident notifications and its response to those incidents was thorough, well balanced, complete, and comprehensive. The team determined the NRC followed its processes and the follow-up of incidents was appropriate. The NRC dispatched inspectors for onsite follow-up for 12 of the 22 cases reviewed. The team noted that the onsite response was thorough and high quality, and that incidents were followed-up on during the subsequent inspection.

During the review period, 93 materials-related allegations were received by the NRC. The team evaluated 14 of those allegations and found that the NRC took prompt and appropriate action in response to the concerns raised. Documentation for each allegation reviewed was complete and thorough. Concerned individuals were notified of the results of the NRC's review, whenever possible.

c. Evaluation

The team determined that, during the review period, the NRC met the performance indicator objectives listed in Section 3.5.a. Based on the criteria in MD 5.6, the team recommends that the NRC's performance with respect to the indicator, Technical Quality of Incident, and Allegation Activities, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

4.0 NON-COMMON PERFORMANCE INDICATORS

Two non-common performance indicators are used to review the NRC's program:(1) SS&D Evaluation and (2) Uranium Recovery Programs.

4.1 Sealed Source and Device (SS&D) Evaluation Program

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides information on conducting the SS&D reviews and establishes useful guidance for teams. In accordance with MD 5.6, three sub-elements: Technical Staffing and Training, Technical Quality of the Product Evaluation Program, and Evaluation of Defects and

Incidents Regarding SS&D's, are evaluated to determine if the SS&D program is satisfactory.

a. Scope

The team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated the NRC's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Qualification criteria for new technical staff are established and are being followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- Management is committed to training and staff qualification.
- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D reviewers are trained and qualified in a reasonable period of time.

Technical Quality of the Product Evaluation Program

- SS&D evaluations are adequate, accurate, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3.

Evaluation of Defects and Incidents

- SS&D incidents are reviewed to identify possible manufacturing defects and the root causes of these incidents.
- Incidents are evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications to the NRC, Agreement States, and others, as appropriate, occur in a timely manner.

b. Discussion

Technical Staffing and Training

At the beginning of the review period, the SS&D program had three qualified SS&D reviewers. During the review period, another individual was qualified as a reviewer. Two SS&D reviewers left the program during the review period, including the newly qualified reviewer, due to promotions, leaving the Program with two qualified SS&D reviewers, at the time of this review. The staff promoted are still in MSST and may be used on an as needed basis. Therefore, the team determined that the SS&D Program had sufficient number of qualified SS&D reviewers to conduct an effective Program. The team determined that the Program has a training and qualification program equivalent to the training requirements identified in Appendix D of the NRC's IMC 1248.

Technical Quality of the Product Evaluation

The NRC has 157 SS&D registrations. The team evaluated 52 of 290 SS&D actions processed during the review period. These actions included amendments, new

applications, inactivations, and registrations transferred from Georgia. Based on the information reviewed, the team determined that the technical evaluation of the applications was adequate, accurate, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3, Revision 2.

As noted in Section 2.0, the team reviewed NRC's actions to address the 2014 IMPEP recommendation regarding missing reference documents related to SS&D Registrations transferred to the NRC from the Georgia program. To address the recommendation NRC staff worked with the State of Georgia and certificate holders to locate the missing reference documents. Staff determined that 19 SS&D registration certificates were missing reference documents. Staff determined that seven of the registration certificates were inactive and immediately transferred to an inactive status. Staff identified and obtained all the missing reference documents. Staff documented the findings in an internal closure in a memorandum dated January 20, 2016. Therefore, the team recommends that this recommendation be closed.

Evaluation of Defects and Incidents Regarding SS&Ds

The team evaluated 153 of 170 SS&D related incidents in the NMED database that occurred during the review period. The team did not identify any generic issues related to defects associated with SS&Ds registered by the NRC.

At the end of the last review period, the NRC noted a large number of leaking electron capture devices (ECD) used in gas chromatographs from the same manufacturer. The NRC analyzed incidents from 1991 - 2014 involving leaking ECDs and determined that these incidents predominantly involved older devices. In 2015, the NRC worked with the ECD manufacturer to shorten the stated working life of these devices in an amendment to the device's registry sheet. Subsequently, the number of leaking ECDs has decreased. The team acknowledged the NRC's efforts to proactively work with the licensee to modify the useful life of the device to reduce the number of leaking sources.

c. Evaluation

The team determined that, during the review period, the NRC met the performance indicator objectives listed in Section 4.1.a. Based on the criteria in MD 5.6, the team recommends that NRC's performance with respect to the indicator, Sealed Source, and Device Evaluation Program, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

4.2 Uranium Recovery Program

The objective is to determine if the NRC's Uranium Recovery Program is adequate to protect public health and safety, and the environment. Five sub-elements are used to make this determination: (1) Technical Staffing and Training; (2) Status of Uranium Recovery Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

a. Scope

The team used the guidance in State Agreements procedure SA-110, "Reviewing the Non-Common Performance Indicator: Uranium Recovery Program," and evaluated the NRC's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- Qualified and trained technical staff are available to license, regulate, control, inspect, and assess the operation, and performance of the Uranium Recovery Program.
- Qualification criteria for new uranium recovery technical staff are established and are being followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing the uranium recovery licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing uranium recovery licensing and inspection activities are adequately qualified and trained to perform their duties.
- Uranium recovery license reviewers and inspectors are trained and qualified in a reasonable period of time.

Status of Uranium Recovery Inspection Program

- The uranium recovery facility is inspected at prescribed frequencies.
- Statistical data on the status of the inspection program are maintained and can be retrieved.
- Deviations from inspection schedules are coordinated between uranium recovery technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections; or a basis has been established for not performing overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner.

Technical Quality of Inspections

- Inspections of uranium recovery licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items, non-compliance, and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors, or senior staff as appropriate, conduct annual accompaniments of each uranium recovery inspector to assess performance and assure consistent application of inspection policies.
- Inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

Technical Quality of Licensing Actions

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Applicable uranium recovery guidance documents are available to reviewers and are followed.
- Essential elements of license applications have been submitted and meet current NRC or Agreement State regulatory guidance (e.g., financial assurance, etc.)
- Uranium recovery license reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Licensing practices for risk-significant radioactive materials are appropriately implemented including fingerprinting orders (10 CFR Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

Technical Quality of Incident and Allegation Activities

- Uranium recovery incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- Onsite responses are performed when incidents have potential health, safety, or security significance.
- Appropriate follow-up actions are taken to ensure prompt compliance by licensees.
- Follow-up inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or the NRC.
- Incidents are reported to the NMED and closed when required information is obtained.
- Allegations are reviewed in a prompt, appropriate manner.
- Concerned individuals are notified of review conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

At the time of the IMPEP review, the NRC reported that the Uranium Recovery Program consisted of 4 conventional mill licenses under various stages of decommissioning: 3 in-situ recovery licenses (1 in standby status and 2 licensed, but never constructed) and 1 former uranium conversion facility. During the review period for the Uranium Recovery Program in DUWP, 14 licenses were transferred to the State of Wyoming on September 30, 2018, when the State assumed regulatory authority over uranium recovery facilities. Licensing actions performed by the Program for those licenses prior to their transfer to the State of Wyoming were included in the scope of this review.

Technical Staffing and Training

In its Uranium Recovery Program, the NRC has 4 qualified staff who perform inspections, 7 qualified staff who perform licensing reviews, and 2 staff in training. During the review period, 2 staff members left the Uranium Recovery Program and

2 new staff were hired. The team determined that the Uranium Recovery Program's staffing levels and staff qualifications for the Uranium Recovery Program was adequate to maintain the Program, and there was a good balance between inspectors and license reviewers. The team determined that the Uranium Recovery Program has a training and qualification program equivalent to the training requirements identified in Appendix H of the NRC's IMC 1248.

Status of the Uranium Recovery Inspection Program

During the review period, the NRC performed 16 inspections. No inspections were performed overdue. However, internal audits conducted in 2018 and 2019 identified a failure to inspect two sites that were licensed but not constructed. To correct this, staff contacted each site annually to verify that site conditions had not changed and documented the results in a memo to the file in ADAMS. The review determined that the NRC completed the uranium recovery inspections in accordance with the frequencies outlined in IMC 2801, Uranium Mill and 11e.(2), Byproduct Material Disposal Site and Facility Inspection Program, and NRC's IMC 2641, In-Situ Leach Facilities Inspection Program.

Inspection findings for the Uranium Recovery Program were communicated by formal correspondence to the licensee within 30 days following the inspection.

Technical Quality of Inspections

The team evaluated all 16 inspections conducted during the review period. These included a variety of uranium recovery inspection activities in different stages of licensed operations. The team found that the inspection reports were thorough, complete, consistent, and had sufficient documentation to ensure that licensee performance with respect to health, safety, and security was acceptable. The findings were well-founded, supported by regulations, were appropriately documented, and performed in accordance with NRC policy. Documentation indicated that the supervisory accompaniments of the inspection staff was performed annually during the review period.

The team determined that the Uranium Recovery Program has an adequate supply of properly calibrated radiation detection equipment to support the inspection program. Calibrations are performed annually. In all inspection records reviewed, the team found that surveys had been performed with properly calibrated survey equipment.

Technical Quality of Licensing Actions

During the review period, NRC staff completed 4 licensing actions: 2 major amendments and 2 renewals. Documentation consisted of decommissioning plans, the modification of a restricted area, designation of a radiation safety officer, a license transfer, annual financial assurance updates, and compliance monitoring. The team found that the work associated with the licensing actions was thorough, complete, consistent, and had sufficient documentation to ensure that licensee performance with respect to health, safety and environmental issues were properly addressed. The findings were supported by regulations, based on sound health physics principles, and appropriately documented.

The team also interviewed staff members about the status of each regulated site and found that management and staff were familiar with the technical details and conditions

existing at each site. The team also evaluated the decision analysis reports for all the licensing actions and found them to be supportive of licensing actions taken.

Technical Quality of Incident and Allegation Activities

During the review period, 4 incidents involving the Uranium Recovery Program were reported to, and evaluated by, the NRC staff. The team found that staff properly evaluated each incident, conducted interviews when appropriate, and thoroughly documented all findings. The team also found that the NRC responded to incidents in accordance with its established procedure.

During the review period, the NRC received 2 allegations and closed 2 allegations received during the previous review period. The team found that the NRC took prompt and appropriate action in response to the concerns. The allegations were appropriately closed, concerned individuals were notified of actions taken, and their identities were protected in accordance with MD 8.8, "Management of Allegations."

c. Evaluation

The team determined that, during the review period, the NRC met the performance indicator objectives listed in Section 4.2.a. Based on the criteria in MD 5.6, the team recommends that the NRC's performance with respect to the indicator, Uranium Recovery Program, be found satisfactory.

d. MRB Chair's Determination

The final report will present the MRB Chair's determination regarding this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, the NRC's performance was found to be satisfactory for all performance indicators reviewed.

The team did not make any recommendations.

Accordingly, the team recommends that the NRC be found adequate to protect public health and safety. Based on the results of the current IMPEP review, the team recommends that the next full IMPEP review take place in approximately 5 years, with a periodic meeting in approximately 2.5 years.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspector Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Areas of Responsibility
Duncan White, NMSS	Team Leader Technical Quality of Incidents and Allegation Activities
Michelle Beardsley, NMSS	Technical Staffing and Training Status of Materials Inspection Program
Shannon Dettmer, OH	Sealed Source and Device Evaluation Program
Sherrie Flaherty, MN	Team Leader in Training Technical Quality of Inspections Inspector Accompaniments
Gehan Flanders, TX	Uranium Recovery Program
Brian Goretzki, AZ	Technical Quality of Incident and Allegation Activities Inspector Accompaniments
James Pate, LA	Sealed Source and Device Evaluation Program
Nancy Stanley, NJ	Technical Quality of Inspections
Angela Wilbers, KY	Technical Quality of Licensing Actions Inspector Accompaniments
Shirley Xu, NMSS	Technical Quality of Licensing Actions Technical Quality of Incidents and Allegations

APPENDIX B

INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the remote IMPEP review:

Accompaniment No.: 1	License No.: 49-26808-02
License Type: Industrial Radiography	Priority: 1
Inspection Date: 04/27/2021	Inspector's initials: LW

Accompaniment No.: 2	License No.: 45-01052-21
License Type: Research and Development Broad (Type A)	Priority: 3
Inspection Date: 06/03/2021	Inspector's initials: JA

Accompaniment No.: 3	License No.: 19-07538-05
License Type: Research and Development Broad (Type A) / Irradiators	Priority: 3
Inspection Date: 06/01/2021	Inspector's initials: MR

Accompaniment No.: 4	License No.: 41-32720-01/41-32720-02MD
License Type: Nuclear Pharmacy	Priority: 2
Inspection Date: 04/15-28/2021 (REMOTE)	Inspector's initials: RG

Accompaniment No.: 5	License No.: 13-02141-01
License Type: Permanent Radiographic Installation	Priority: 2
Inspection Date: 4/13 – 5/14/2021 (REMOTE)	Inspector's initials: JD

Accompaniment No.: 6	License No.: 29-03405-02
License Type: Industrial Radiography	Priority: 1
Inspection Date: 05/10/2021	Inspector's initials: SC

Accompaniment No.: 7	License No.: 37-28358-01
License Type: Industrial Radiography	Priority: 1
Inspection Date: 05/12/2021	Inspector's initials: JP

Accompaniment No.: 8	License No.: 47-18046-01
License Type: Medical Institution – Diagnostic and Therapeutic	Priority: 3
Inspection Date: 05/20/2021	Inspector's initials: ETE

Accompaniment No.: 9	License No.: 07-16199-02
License Type: Medical Therapy – Other Emerging Technologies	Priority: 2
Inspection Date: 05/24/2021	Inspector's initials: JN

Accompaniment No.: 10	License Nos.: 19-08330-02 & 19-08330-03
License Type: Research & Development -Type A Broad scope	Priority: 1
Inspection Date: 05/25/2021	Inspector's initials: RR